



EUROTHERM

2327 02 JUL 2002 19:48
JL CONTROLS
PROCESS AUTOMATION
RECORDERS

Dockets Management Branch (HFA-305),
Food and Drug Administration
5630 Fishers Lane,
Room 1061
Rockville,
MD 20852

25 June, 2002

Dear Sir/Madam

Re: Comments on the "Draft Guidance for Industry 21CFR Part 11; Electronic Records; Electronic Signatures Time stamps"

Please find below Eurotherm's comments on the "Draft Guidance for industry 21 CFR Part 11; Electronic Records; Electronic Signatures Time Stamps".

1. Timestamp accuracy should be documented as part of the system.
2. If time synchronization is configured as an automatic process then failures to receive time synchronization events at the expected frequency must be recorded in the audit trail - for instance if the time server becomes unavailable.
3. When using an automated time synchronization method the system should track that time synchronization times are within acceptable bounds. If time is out by more than the documented accuracy of the system on receipt of a time sync message then this should be recorded in the audit trail. This ensures that network latencies or clock drift don't allow errors of more than a known magnitude to occur.
4. Inappropriate changes to computer clocks must be detected. Standard Operating Procedure's must be in place to detect and deter inappropriate changes to computer clock."

000-1542

C8

Eurotherm Limited

Faraday Close Durrington Worthing BN13 3PL United Kingdom
General Enquiries: Tel.+44 (0)1903 268500 Fax +44 (0)1903 265982
Email: info@eurotherm.co.uk www.eurotherm.co.uk

Sales and support

CONTROLS Tel.+44 (0)1903 695888 Fax+44 (0)1903 695666
PROCESS AUTOMATION Tel.+44 (0)1903 205277 Fax.+44 (0)1903 233902



EUROTHERM

CONTROLS
PROCESS AUTOMATION
RECORDERS

I hope you find the above comments useful. If you have any queries please don't hesitate to contact me.

Yours Sincerely,

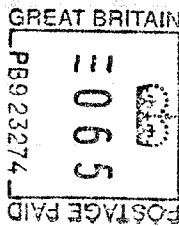
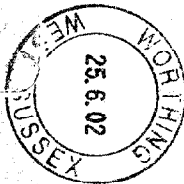
Matt Safi
Pharmaceutical Marketing Manager

AIR MAIL



Eurotherm Ltd
Faraday Close Durrington Worthing
West Sussex BN13 3PL United Kingdom

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rocksville
MD20852



20857+0001

